JUN 0 6 2014

K133774

Summary of safety and effectiveness

In accordance with Section 513 (1) of the SMDA as defined in 21CFR part 807.3 this summary is submitted to obtain Pre-Market 510 (K) notification.

Prepared on May 28, 2014

1. Manufacturer

DIOTECH CO LTD will register after cleared
#212, Ildongjiaenin, GeoJeong 4 dong, Saha gu,
Busan, Rep of Korea
Tel: 82 51 292 6236 F 82 51 292 6238

2. Submitter, Correspondent

Young Chi
Bio-Med USA Inc.
111 Ellison Street, Paterson, NJ07505. U.S.A
Tel: 973 278 5222 Fax 201 934 6030
e mail: biomedusa@msn.com

3. Name of Device

Trade name	:	**ATOVEN**
Classification name :	:	Powered, Laser surgical instrument
Classification panel	:	General & Plastic Surgery
Common name	:	Diode laser system
Regulation	:	880.4810 Class II
Product Code	:	GEX

4. Legally marketed Predicate Device

K110364 LiteBeam+1470 Dornier MedTech

5. Intended use

ATOVEN is a diode laser system designed to delivery of laser light to soft tissue during general surgery procedures. This device intended for treatment of reflux of the saphenous veins associated with varicose veins and varicosities.
Non-Contact mode

6. Device Description

ATOVEN Diode laser systems are Laser Surgery Systems that use optical energy radiated from semiconductor laser in order to cure varices. with Wave Length 1,470nm, and consists of CPU, LCD monitor, Cooling Systems, laser controller, Fiber optic pull-back device included foot pedal switch.
LED monitor are displaying various graphic to shows Operating Parameter, Mode, Time function, system status to user.

7. Non-Clinical Data.

No clinical standards have been established for Diode Laser,
but did Safety and Performance test in accordance with below Standard.

IEC 60601-1 Medical Electrical Equipment part 1
General Requirement for safety amend 2:1995
IEC 60601-1-2 Electromagnetic compatibility test ED 2007
IEC 60601-1-2-22: 1996 Particular requirement for the safety and Diagnostic of Therapeutic laser Equipment
IEC60825_1 Safety of laser products Part 1, section 2, Manufacturing requirement.

8. Sterilization and Biocompatibility information

This submission does not included any fiber, catheters, Guide Wire etc,
accordingly no need any Sterilization and Biocompatibility information.

9. Conclusion.

ATOVEN Diode laser system, in this submission, is substantially equivalent to several already cleared predicate device in respect to Intended use, Main function, Technology, Principal operation and performance.

So, it does not raise any additional concerns regarding safety and effectiveness.

Bio-Med USA will update and include in this summary any other information deemed seasonally necessary by the FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

Bio-Med USA Incorporated
Mr. Young Chi
President
111 Ellison Street
Paterson, New Jersey 07505

Re: K133774
Trade/Device Name: ATOVEN
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 2, 2014
Received: May 8, 2014

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133774

Device Name
ATOVEN

Indications for Use *(Describe)*
ATOVEN is a diode laser system designed to delivery of laser light to soft tissue during general surgery procedures. This device intended for treatment of reflux of the saphenous veins of thigh associated with varicose veins and varicosities.
Non-Contact mode

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.06.06 11:53:13 -04'00'

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